

**REMARKS**

The Office Action mailed May 28, 2008 set an initial three (3) month period for response; Submitted herewith is a Petition for a Three Month Extension of Time and a request that Deposit Account 04-1679 be charged for the required fee. Accordingly, this Response is timely filed, with a Three Month Extension of Time up to November 28, 2008.

Claims 129 to 171 are pending. Applicants note that claims 161 to 171 stand withdrawn from consideration as directed to a non-elected invention.

Applicants reiterate their traverse of the restriction requirement set forth in their Response mailed March 14, 2008, and request that the Examiner reconsider the restriction requirement in view of this submission and the traverse in their previous Response and withdraw it.

**The Section 112 First Paragraph Rejection (New Matter) At Page 2**

Claims 146 to 161 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. This rejection is traversed.

The Examiner asserts that "[t]he original disclosure as filed does not support the limitation where triethylenetetramine and succinic acid are purified" (see May 28, 2008 Office Action, page 2).

Applicants submit that the Examiner's position is not well taken and that claims 146 to 161 give rise to no issue of new matter. Applicants note the Examiner's reference to page 81 regarding purified water appears to refer to preparation of reagents used for GF-AAS analysis and not to preparation of acid addition salts and, thus, appears to be out of context.

Applicants note that the application at page 30 (all page references are the published PCT Application, WO 2004/017956 upon which this United States Application is based) describes preparation of acid addition salts of trientine by reaction of trientine and acid (such as succinic acid) in an inert solvent and subsequent removal of the solvent (such as by evaporation) to give a dry salt, which inherently provides a purified acid addition salt.

Applicants request that the Examiner reconsider this rejection and withdraw it.

**The Section 112, First Paragraph, Rejection (Written Description) At Page 3**

Claims 160 and 161 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly not complying with the written description requirement. Applicants submit that the Examiner's position is not well taken and traverse this rejection.

The Examiner appears to object to the terms "delivery agent" and "reverse active transport agent".

Applicants note that the application provides ample description and exemplification of "delivery agent" and "reverse active transport agent". See, e.g. pages 73 to 77 of the Application.

Moreover, Applicants submit that agents useful for use as a "delivery agent" and/or a "reverse active transport agent" would be known to one of skill in the pharmaceutical formulation arts.

Accordingly, applicants submit that claims 160 and 161 clearly comply with the first paragraph of Section 112. Applicants request that the Examiner reconsider this rejection and withdraw it.

**The Section 103 Rejection**

Claims 129 to 161 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over published United States Patent Application US 2003/0055113 to Wang et al. ("Wang et al").

This rejection is traversed. Wang et al neither suggest nor make obvious the subject matter of claims 129 to 161.

Applicants are investigating whether Wang et al constitute properly citable prior art against the present application. Applicants' traverse of the rejection over Wang et al is not an acknowledgement that Wang et al constitutes properly citable prior art.

Even should Wang et al constitute properly citable prior art under 35 U.S.C. §§ 102 and 103, applicants submit that Wang et al neither suggest nor make obvious the subject matter of claims 129 to 161.

Wang et al are concerned with methods for treating ocular inflammation, particularly inflammation secondary to laser therapy of choroidal neovascularization. (See, e.g. Wang [0006]). Wang et al are also concerned with pharmaceutical compositions adapted to ocular

administration and which use “an ophthalmologically acceptable carrier”. The Examiner admits at page 6 in The Office Action mailed May 28, 2008 that Wang et al do not teach that “[t]he specific salt is formed from succinic acid” (page 6) and “the Examiner acknowledges that ‘picking and choosing’ within several variables does not necessarily give rise to anticipation” (page 7). The Examiner further admits “where, as here, the reference does not provide any motivation to select this specific combination of variables, anticipation cannot be found” (page 7).

Applicants note that the Examiner’s apparent justification for the present rejection (citing KSR v. Teleflex 127 S.Ct 1727, 1741(2007)) is as follows:

The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Idm at 1742. Consistent with this reasoning, it would have obvious to have selected succinic acid from the list of organic acids disclosed by the prior art to form a salt of triethylenetetramine, to arrive at compositions “yielding no more than one would expect from such an arrangement”.

May 28, 2008 Office Action, page 7. Applicants note that the Examiner fails to provide any motivation to select succinic acid from any list of

organic acids. Merely asserting it would be “obvious” without giving any reason, rationale or motivation does not suffice to render it so.

In view of the different contemplated uses of Wang et al for their ophthalmic compositions and, when considered in the context of what Wang et al would fairly teach or make obvious to one of skill in the art, the present rejection over Wang et al should not stand. Applicants request that the Examiner reconsider the present rejection and withdraw it.

### **CONCLUSION**

Applicants submit that, in view of the foregoing, Claims 129 to 161 are allowable. Applicants submit that withdrawn claims 162 to 171 are allowable as well. Applicants request that the claims be allowed and passed to issue.

Should any issues or questions remain, or if the Examiner believes that a telephone interview would expedite prosecution and allowance of this application, the Examiner is encouraged to telephone the undersigned applicants’ attorney at (619) 744.2210.

Commissioner is hereby authorized to charge any requisite fees for this submission, or any fees in connection with this application during its entire pendency, or to credit any overpayment, to Deposit Account No. 04-1679.

Dated: November 28, 2008

Respectfully submitted,

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